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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER

COLLINS, CYNTHIA E

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 08/27/2003

68

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,679

Applicant(s)

PAUL ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26, 28, 29 and 31 is/are pending in the application.
- 4a) Of the above claim(s) 9, 17-24, 28 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10-16, 25, 26 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The Amendment filed June 16, 2003, paper no.14, has been entered.

Claims 27 and 30 are cancelled.

Claims 1-8, 10-13, 15-16 and 25 are newly amended.

Claim 31 is newly added.

Claims 1-26, 28-29 and 31 are pending.

Claims 9, 17-24 and 28-29 are withdrawn from consideration.

Claims 1-8, 10-16, 25-26 and 31 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Information Disclosure Statement

An initialed and dated copy of Applicant's IDS form 1449, filed February 22, 2001, Paper No. 8, is attached to the instant Office action.

Claim Rejections - 35 USC § 112

Claims 4 and 25 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed January 15, 2003.

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Applicant's arguments filed June 16, 2003, have been fully considered but they are not persuasive.

Applicant argues that the rejection is rendered moot by the amendment of claim 1 to recite that the nucleic acid encodes the protein of claim 15 (reply page 7).

The Examiner maintains that the amendment of claim 1 to recite that the nucleic acid encodes the protein of claim 15 does not render the rejection of claims 4 and 25 moot because the specification does not describe the structure of nucleic acids encoding functional proteins having at least 80% amino acid sequence identity to SEQ ID NO:15 and comprising an amino acid sequence in which one or more amino acid deletions, insertions or substitutions has been made in SEQ ID NO:15.

Claim 5, and claims dependent thereon, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 is indefinite in reciting "the isolated nucleic acid of claim 1 which comprises the sequence of SEQ ID NO:15", as the sequence listing indicates that SEQ ID NO:15 is an amino acid sequence, not a nucleic acid sequence.

Claim Rejections - 35 USC § 101 and 35 USC § 112

Claims 1-8, 10-16 and 25-26 remain rejected, and claim 31 is rejected, under 35 U.S.C. 101, because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility, for the reasons of record set forth in the office action mailed January 15, 2003.

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Applicant's arguments filed June 16, 2003, have been fully considered but they are not persuasive.

Applicants assert that the cited reference of Doerks et al. is a general article that does not provide specific examples of the homology and identity ranges used in their study, and does not provide the homology of predicted functional regions. Applicants further point out that it is asserted in the specification at page 24 that DZ2 possesses the conserved amino acid residues required for the phosphorylation of the receiver domain of the response regulator component. Applicants argue that having the conserved residues required for phosphorylation of the receiver domain of the response regulator component is a key indicator of function, and that no further evidence is needed (reply pages 8-9).

The Examiner maintains that the Doerks et al. reference was appropriately cited in support of the assertion that general structural homology between amino acid sequences is not always predictive of their functional homology. The Examiner also agrees that the existence of specific structural homology in polypeptide domains known to be required for protein function can be predictive of functional homology between structurally homologous amino acid sequences. The Examiner acknowledges that it is asserted in the specification at page 24 that DZ2 possesses the conserved amino acid residues required for the phosphorylation of the receiver domain of the response regulator component, but maintains that having the conserved residues required for phosphorylation of the receiver domain of the response regulator component is a not necessarily a key indicator of function, such that further evidence is needed to support the utility of the DZ2 polypeptide. While the prior art teaches that response regulators contain a shared domain having at least 2 aspartic acid residues and a lysine residue, and that the histidine kinase component of two-component signal transduction systems phosphorylates the

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response regulator on a specific aspartic acid residue, the prior art also teaches that the activities of other response regulator domains are controlled by phosphorylation of the conserved receiver domain (Alex et al., Trends in Genetics, April 1994, Vol. 10, No. 4, pages 133-138, see page 135 column 1 first full paragraph and paragraph spanning column 1 and 2). For example, phosphorylation of the CheB receiver domain activates a CheB methylesterase activity, whereas phosphorylation of the OmpR receiver domain increases the efficiency of OmpR DNA binding (Alex et al. page 135 column 2 lines 4-8). Accordingly, phosphorylation of the receiver domain of the response regulator component is a not necessarily a key indicator of function, as the phosphorylation serves to control the activities of other response regulator domains, which differ in both structure and function between different response regulators.

In response to the prior assertion by the Examiner that the specification does not disclose a signal transduction function for protein encoded by the claimed nucleic acid, and that the disclosure does not teach how the claimed nucleic acid or the protein it encodes would be beneficial to the public, Applicants respond that they are not aware of a necessity for proving that an invention must benefit the public, and maintain that they need only teach a utility for the invention. Applicants further argue that there is ample support for a signal transduction function for the encoded protein, as discussed previously. Applicants additionally argue that reference to the cited case of Brenner is misguided, as applicants have demonstrated that the nucleic acid of sequence of SEQ ID NO:14 encodes a protein which is involved in plant dehiscence, and that in light of this disclosure, the role of the claimed polypeptide in signal transduction is irrelevant to the utility of the claimed invention (reply page 9).

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The Examiner does not dispute that Applicants need only teach a utility for the invention, and maintains that it is the teaching of a utility for the claimed invention that is the beneficial to the public. The Examiner does not agree, however, that a utility for the claimed invention has been demonstrated. First, the Examiner does not agree that a signal transduction function for the encoded protein is supported, as discussed *supra*. Second, while demonstrating that the nucleic acid of sequence of SEQ ID NO:14 encodes a protein involved in plant dehiscence would also constitute an acceptable utility, the Examiner does not agree that a plant dehiscence function has been demonstrated. It is acknowledged that the specification teaches that the DZ2 cDNA hybridizes to an mRNA transcript that is specifically expressed in the dehiscence zone, but such a correlation is not necessarily indicative of a plant dehiscence function for the DZ2 protein, as the expression of the mRNA may be coincident with the dehiscence process, since correlation is not equivalent to cause and effect.

Claims 1-8, 10-16 and 25-26 remain rejected, and claim 31 is rejected, under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, for the reasons of record set forth in the office action mailed January 15, 2003.

Applicant's arguments filed June 16, 2003, have been fully considered but they are not persuasive.

Applicants reiterate that there is a well established utility for the claimed invention as previously discussed, and that one skilled in the art would know how to use the claimed invention. Applicants point out that the specification discloses in Example 1 the isolation and

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characterization of SEQ ID NOS: 14 and 15, and that the specification discloses in Example 2 the isolation and characterization of a close homolog. Applicants further point out that while the examples discussing downregulation of the expression of SEQ ID NO:14 may be prophetic, that antisense gene regulation is well known in the art and can be practiced by the skilled artisan without undue experimentation (reply page 10).

The Examiner maintains that because a utility for the claimed invention has not been established, as discussed *supra*, one skilled in the art would not know how to use the claimed invention. As Applicant has not established a specific and substantial or well established utility for SEQ ID NOS: 14 and 15, or the disclosed homolog, the predictability of downregulating the expression of SEQ ID NO:15 cannot be assessed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Remarks

No claim is allowed.

Claims 5, 16, 27 and 30 are deemed free of the prior art due to the failure of the prior art to teach or suggest an isolated nucleic acid molecule of SEQ ID NO:14 or encoding SEQ ID NO:15, or plant cells or plants transformed therewith.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (703) 605-1210. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196

CC
August 15, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

